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EXAMINER	
SISSON, B	
ART UNIT	PAPER NUMBER
1807	7
DATE MAILED:	10/15/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

## Office Action Summary

Application No.

08/791,240

Applicant(s)

Alexander J. Ryncarz

Examiner

Bradley L. Sisson

Group Art Unit

1807

 Responsive to communication(s) filed on 19 Aug 1997. This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 1-57 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 1-57 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### *Specification*

1. The communication filed on 19 August 1997 is not fully responsive to the communication mailed 29 July 1997 for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within the time period set with the mailing of this Office action.

### *Claim Rejections - 35 USC § 112*

2. Claims 1-6, 11-13 and 25-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 and 25-52 are confusing with respect to the names provided, or rather, not provided to the various primers which are used in the claimed method. With no clear indication as to which primer is being used at any given time, and with the primers being referred to as "said primer," it is rather confounding as to just how many primers are in the reaction.

Claims 4, 11, 27, 41, and 53 are indefinite with respect to just what constitutes "substantially." Claims 5 and 6 which depend from claim 4; claims 12 and 13 which depend from claim 11; claims 28

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and 29 which depend from claim 27; claims 42 and 43 which depend from claim 41; and claims 54-57 which depend from claim 53 fail to overcome this issue and are similarly indefinite.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis et al., in view of Kiessling, Davis et al., and Gillespie.

5. Mullis teaches at length conditions for performing polymerase chain reaction (PCR), including the selection and manufacture of primers; the types of sources from which a nucleic acid sample can be obtained; temperature cycling; repeated cycles of primer extension, annealing, dissociation, etc.; the performance of PCR with nested primers; see column 25, Example 10.

Mullis does not disclose the use of a primer which has a 3' terminal portion which does not anneal to a target/control sequence and which is selectively cleaved with a 3' to 5' exonuclease.

Kiessling, column 13, penultimate paragraph, discloses performing PCR where one incorporates into the reaction a positive control nucleic acid sequence. Kiessling also discloses kits that can be formulated; see column 8, first full paragraph.

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6. Kiessling does not disclose the use of primers which have an intentionally non-annealing 3' terminal portion and which is selectively cleaved with a 3' to 5' exonuclease.

7. Davis et al., disclose the use of a primer which has an intentionally non-annealing 3' terminal portion which is cleaved through the action of a 3' to 5' exonuclease; see Fig. 2. As seen in column 2, first full paragraph, and at column 5, lines 44-45, the use of a 3' to 5' exonuclease is preferred to remove the non-annealing terminal nucleotide. Column 6 discloses a variety of detectable labels that may be incorporated into the nucleotide.

8. Davis et al., do not define the non-annealing terminal portion of the primer a being that which is from 1 to 10 nucleotides in length.

9. Gillespie disclose the use of two primers where one of said primers has an intentionally non-annealing 3' portion. Column 4, first full paragraph states that the primer is 20-50 nucleotides in length and with a non-complementary portion that is preferably 5-10 nucleotides in length.

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the primer disclosed by Gillespie with the method of Davis et al., Kiessling and Mullis so to achieve a positive control for a PCR reaction where one would be able to determine if the control primer was functioning in the manner intended, and by extension, determine if the PCR reaction as a whole was proceeding correctly. In view of the guidance provided in the art, and the explicit recitation of using primers which have an intentional non-annealing overhang in such PCR reactions, the ordinary artisan would have been motivated to have combined such teachings and to have done so with a reasonable expectation of success. The aspect of combining the requisite

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reagents in a kit as disclosed by Kiessling would have been an obvious commercial expediency, requiring little if any additional research and development. Accordingly, and in the absence of convincing evidence to the contrary, the claimed invention is *prima facie* obvious in view of the prior art of record.

***Conclusion***

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone numbers for Group 1800 are (703) 305-3014 and (703) 305-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*B. L. Sisson*

BRADLEY L. SISSON  
PRIMARY EXAMINER  
GROUP 1800

9.30.97